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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,325	09/12/2005	Jerome B Zeldis	9516-207-999	9771

7590

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/534,325	Applicant(s) ZELDIS, JEROME B	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Restriction is required under 35 U.S.C. 121 and 372.

Group I, claim(s) 1-2, 5-6, 10-24, drawn to a method of treating managing and preventing cancer administering a selective cytokine inhibitory drug classified in class 514/210.02

Group II, claim(s) 3-4 and 7 drawn to treating managing and preventing angiogenesis administering a selective cytokine inhibitory drug classified in class 514/ 423

Group III, claim(s) 27-32, drawn to a pharmaceutical composition comprising a selective cytokine inhibitory drug classified in class 514/101

The inventions are distinct, each from the other because of the following reasons:

Inventions III is related to groups I and II as product and alternative processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case treating cancer can be carried out using thalidomide drugs (see British Journal of cancer Press release).

Groups I and II are patentable distinct and/or independent Process of use. The reasons are as follows: different patient population, different out comes, for example an inhibitor of angiogenesis can be used to treat psoriasis and different class and subclasses.

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Claims 8 and 9 link species of the instant invention. Upon the allowance of the linking claim(s), the species election requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additionally, Applicant is required to make an election of one of the Groups above and further, in addition, Applicant is required to make an election of one species therein as discussed below.

The practice, re: Markush claims encompassing multiple independent and patentably distinct inventions is set for the in M.P.E.P. 803. The following requirement to make a provisional election of a single independent and patentably distinct invention is made pursuant to said practice.

Claim 5 –9, 14, 16, 18, 29 and 31 drawn in Markush format encompass multiple and patentably distinct inventions. The claims are either drawn to different compounds and combinations as well as the treatment of a variety of diseases as shown below. The practice, re: Markush claims encompassing multiple independent and patentably distinct inventions is set for

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the in M.P.E.P. 803. The following requirement to make a provisional election of a single independent and patentably distinct invention is made pursuant to said practice.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for each of formula (I) and formula (II) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Further, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to define each of R^1 , R^2 and n and any additional variables as required for a particular species. Further, Applicant is required to also elect a single disclose treating condition (disease).

Additionally, Applicant is required to make an election of one of the Groups above and further, in addition, Applicant is required to make an election of one species therein as discussed below.

The groups above are set forth in order of precedence in the claims. Any specie/compound/composition having the distinguishing feature set forth in one of the above groups will be contained in that group regardless of the fact that it may also contain a feature set forth in a group of lower precedence.

It is considered that at Markush type claim encompassing such species is directed to multiple independent and patentably distinct inventions since the species are so unrelated and diverse that a prior art reference anticipating the claims with respect to one of the species will not render the claim anticipated or obvious under 35 U.S.C. 102 nor 35 U.S.C. 103 respectively with regard to any one other of the species. Further these species are considered to be independent since they are unconnected in operation, one does not require the others for ultimate use and the

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specification does not disclose a dependent relationship between them. Moreover, each of the stated species is considered patentably distinct from the others on the basis of its properties.

Thus, the stated species are capable of supporting separate patents under 35 U.S.C. 121.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election/Restrictions Proper

MPEP §809.02(d) states “[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary.”. Here, the claims recited

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such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

Example, present claim 13 provides a variety of possibilities for R^1 , R^2 , and n . For hypothetical exemplification purposes only, if each of the variables above were each limited to 10 possible moieties there would be 10^9 possible species of compounds to be searched.

Further, as shown by the following classifications, a majority of the combinations encompassed by the present claims has acquired a separate status in the art. For example, if there is a 6 membered ring containing one N it is classified in class 514 subclass 277 whereas if there is a 6 membered ring containing two Ns it is classified in class 514 subclass 247. Notwithstanding that the classification of some of the active agents is co-extensive, all of the claimed compounds are patently distinct and fully capable of supporting separate patents.

For the above reasons, an election of a single disclosed species for examination purposes is deemed necessary and proper.

Applicant's response must include a provisional election of one of the independent and patentably distinct inventions identified above even though the requirement is traversed (37 C.F.R. 1.142 and 1.143). Applicant is advised that any traverse must be supported by argument in order to perfect the right to petition in the event that the provisional requirement is given effect in the event noted above.

If Applicant elects either group I or II or III, claims 8 and 9 will be examined with the elected group.

Regardless of which type of disease and further which Invention Applicant elects, Applicant is additionally required to elect a species of the compound of group I, for search purposes.

A shortened statutory period for response to this action is set to expire 30 days from the date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
3/14/06


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